



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 15, 2017

Sheffield Pharmaceuticals
Kathleen Hacku
Quality Assurance Manager
170 Broad Street
New London, CT 06320

Re: K073684
Trade/Device Name: Sheffield Brand Sterile LubriGel
Regulation Number: 21 CFR 880.6375
Regulation Name: Patient Lubricant
Regulatory Class: I
Product Code: KMJ
Dated: April 8, 2008
Received: April 14, 2008

Dear Kathleen Hacku:

This letter corrects our substantially equivalent letter of May 22, 2008.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely,

 Tina
Kiang -S

Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) INDICATIONS FOR USE FORM
(Replica of FDA Form)

510 (k) Number (if known): K 073684

Device Name: Sheffield Pharmaceuticals (Sterile) LubriGel

Indications for Use:

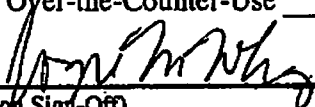
Patient lubricant intended for medical purposes to lubricate orifices to facilitate the entry of diagnostic and therapeutic devices. The device is intended for use on order of a physician.

Non-Prescription Over-the-counter Use

(PLEASE DO NOT WRITE BELOW THIS LINE CONTINUE ON AN OTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ **OR Over-the-Counter-Use** V
(per 21 CFR 801.109)


(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices

510(k) Number K073684



MAY 22 2008

K073684

510(k) Summary

Applicant: Faria Limited, LLC dba Sheffield Pharmaceuticals
170 Broad Street
New London, Ct. 06320 USA

Signature of Applicant:

Thomas H. Faria - President

THF

5/21/08

Date

Phone: (860) 442-4451
Fax: (860) 442-0356

Contact: Kathleen Hacku
Quality Assurance Manager

Date: December 15, 2007

Manufacturing Site:

Faria Limited, LLC dba Sheffield Pharmaceuticals
170 Broad Street
New London, Ct. 06320 USA

Registration Number: 1210513

Device Class: Class I (reserved)

- **Trade Name:** Sheffield Pharmaceuticals LubriGel
- **Common Name:** Personal Lubricant
- **Classification Name:** Patient Lubricant
- **C.F.R. section:** 21 CFR section 880.6375

Classification Panel: Obstetrical/Gynecological

New Device's Name: Sheffield Pharmaceuticals Sterile LubriGel

Predicated Device(s):

E-Z Lubricating Jelly (Sterile), manufactured by Chester Labs Inc. (K041060)

PDI Lubricating Jelly (Sterile), manufactured by Nice-Pak Products, Inc. (K974768)

Information supporting claims of substantial equivalence, as defined under the Federal Food Drug and Cosmetic Act, with respect to safety and effectiveness is summarized below. For the convenience of the reviewer, this summary is formatted in accordance with the Agency's final rule, "510(k) Summaries and 510(k) Statements" (21 CFR 807).

Intended Use:

Sheffield Pharmaceutical Sterile LubriGel is a medical device intended for medical purposes to lubricate body orifices to facilitate the entry of diagnostic and therapeutic devices.

Device Description:

Sheffield Pharmaceuticals Sterile LubriGel patient lubricant is a water-based, clear, colorless, odorless, non-sticky, non-greasy, non-staining, non-irritating patient lubricant. It is a water soluble, high viscosity gel-like liquid for use as patient lubricant when a sterile field is required.

Each tube is terminally sterilized. The product is sterile unless package is opened or damaged with label directions to discard after use.

The product is packaged in a convenient 4.0 oz laminate tube with a flip top cap and peel seal.

This product is not a contraceptive and does not contain a spermicide.

Regulatory Status:

As per 21CFR, 880.6375, Patient Lubricant is defined as a Class I medical device intended for medical purposes that is used to lubricate a body orifice to facilitate entry of a diagnostic or therapeutic device. Patient lubricants are not exempt from 510(k) clearance.

Technological Characteristics:

Sheffield Pharmaceuticals Sterile LubriGel formula is proprietary. The product has no exceptional technological characteristics and consists mainly of safe water soluble GRAS status ingredients, similar to PDI (Sterile) Lubricating Jelly, and E-Z Lubricating Jelly currently on the market. Sheffield's (Sterile) LubriGel contains: Water, Natural Glyccrin, Peg 6, Carbopol, Peg 32, Sodium Hydroxide, Methylparaben and Propylparaben.

Summary of Technological Characteristics:

Sheffield Pharmaceuticals Sterile LubriGel has been shown, in laboratory test, to be substantially equivalent to the current marketed F-Z Lubricating Jelly and PDI (Sterile) Lubricating Jelly.

Biocompatibility Studies

Biocompatibility Studies on Sheffield's Sterile LubriGel was conducted by outside laboratories, in compliance with Good Laboratory Practices (GLPs) demonstrated:

- In Delayed Contact Dermal Sensitization Test (Buehler Method) the product was considered a non-sensitizer.
- In Vitro Cytotoxicity L929 Agar Overlay Test the product meet the requirements for the test.
- Primary Dermal Irritation in Rabbits determined that the product is not a dermal irritant.
- Single Dose Oral Toxicity in Rats showed the oral LD₅₀ of Sheffield's Sterile LubriGel as greater than 5000 mg/kg of body weight. Therefore, the test article is not toxic.

Laboratory testing conducted on Sheffield Pharmaceutical Sterile LubriGel has provided scientific evidence that this product is safe for its intended use and substantially equivalent to the predicated E-Z Lubricating Jelly (Sterile), and PDI Lubricating Jelly (Sterile).